

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and

Commercialization of CRISPR-Engineered T Cell Therapies for the Treatment of

Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Neogene Therapeutics, Inc. ("Neogene"), headquartered in Santa Monica, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5484; E-mail: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

GROUP A

- United States Provisional Patent Application No. 62/084,654, filed November 26, 2014 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-0-US-01];
- 2. PCT Application No. PCT/US2015/062269, filed November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-PCT-01];
- Australian Patent No. 2015353720, issued June 11, 2020 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-AU-02];
- Canadian Patent Application No. 2,968,399, effective filing date of November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-CA-03];
- 5. Chinese Patent Application No. 201580070673.7, effective filing date of November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-CN-04];
- European Patent No. 3223850, issued January 8, 2020, entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-EP-05];
 - a. Validated in the following jurisdictions: AT, BE, CH, CZ, DE, ES, FR, GB,GR, IE, IT, NL, NO, PL, PT, SE, SI, SK, TR
- Israeli Patent Application No. 252258, effective filing date of November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-IL-06];
- Japanese Patent No. 6863893, issued April 5, 2021 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-JP-07];
- Korean Patent Application No. 2017-7017289, effective filing date of November 24,
 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-KR-08];

- Mexican Patent No. 384919, issued July 29, 2021 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-MX-09];
- 11. New Zealand Patent Application No. 732045, effective filing date of November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-NZ-10];
- Saudi Arabian Patent No. 7697, issued March 11, 2021 entitled "Anti-Mutated KRAS
 T Cell Receptors" [HHS Reference No. E-028-2015-1-SA-11];
- 13. Singapore Patent Application No. 11201704155U, effective filing date of November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-SG-12];
- 14. United States Patent Application No. 15/528,813, effective filing date of November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-US-13];
- 15. Hong Kong Patent No. 1243642, issued January 22, 2021 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-HK-14];
- European Patent Application No. 20150279.6, filed January 3, 2020 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-EP-15];
- 17. Singapore Patent Application No. 10201913978R filed December 31, 2019 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-SG-16];
- 18. Australian Patent Application No. 2020203465, filed May 26, 2020 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-AU-36];
- 19. Saudi Arabian Patent Application No. 520420365, filed October 15, 2020 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-SA-37];
- 20. Hong Kong Patent Application No. 42020021375.9, effective filing date of November 24, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-HK-38];

- 21. Japanese Patent Application No. 2021-063092, filed April 1, 2021 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015-1-JP-40];
- 22. United States Provisional Patent Application No. 62/171,321, filed June 5, 2015 entitled "Anti-Mutated KRAS T Cell Receptors" [HHS Reference No. E-180-2015-0-US-01];
- 23. United States Provisional Patent Application No. 62/218,688, filed September 15, 2015 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-US-01];
- 24. PCT Application No. PCT/US2016/050875, filed September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-PCT-02];
- 25. Australian Patent No. 2016323017, issued February 25, 2021 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-AU-03];
- 26. Canadian Patent Application No. 2,998,869, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-CA-04];
- 27. Chinese Patent Application No. 201680058891.3, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-CN-05];
- 28. European Patent No. 3350213, issued March 31, 2021 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-EP-06];
 - a. Validated in the following jurisdictions: BE, CH, DE, DK, ES, FR, GB, IE, IT,
 NL, NO and SE.

- 29. Israeli Patent Application No. 257840, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-IL-07];
- 30. Japanese Patent Application No. 2018-513423, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-JP-08];
- 31. Korean Patent Application No. 2018-7010326, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-KR-09];
- 32. Mexican Patent Application No. MX/a/2018/003062, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-MX-10];
- 33. New Zealand Patent Application No. 740714, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-NZ-11];
- 34. Saudi Arabian Patent Application No. 518391109, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-SA-12];
- 35. Singapore Patent Application No. 11201802069U, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-SG-13];
- 36. United States Patent No. 10,556,940, issued February 11, 2020 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-US-14];

- 37. Hong Kong Patent Application No. 19100263.9, effective filing date of September 9, 2016 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-HK-15];
- 38. United States Patent Application No. 16/739,310, filed January 10, 2020 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-US-16];
- 39. Singapore Patent Application No. 10201913868X, filed December 30, 2019 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-SG-17];
- 40. Australian Patent Application No. 2021200833, filed February 10, 2021 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-AU-18];
- 41. European Patent Application No. 21162567.8 filed March 15, 2021 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-EP-19];
- 42. Saudi Arabian Patent Application No. 521421309, filed February 23, 2021 entitled "T Cell Receptors Recognizing HLA-CW8 Restricted Mutated KRAS" [HHS Reference No. E-265-2015-0-SA-20];
- 43. United States Provisional Patent Application No. 62/369,883, filed August 2, 2016 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-US-01];
- 44. PCT Application No. PCT/US2017/044615, filed July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-PCT-02];
- 45. Australian Patent Application No. 2017306038, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-AU-03];

- 46. Canadian Patent Application No. 3,032,870, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-CA-04];
- 47. Chinese Patent Application No. 201780059356.4, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-CN-05];
- 48. European Patent Application No. 17749580.1, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-EP-06];
- 49. Japanese Patent Application No. 2019-505220, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-JP-07];
- 50. United States Patent No. 10,611,816, issued April 7, 2020 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-US-08];
- 51. Israeli Patent Application No. 264425, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-IL-09];
- 52. Korean Patent Application No. 2019-7005837, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-KR-10];
- 53. Singapore Patent Application No. 11201900654Q, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-SG-11];
- 54. Hong Kong Patent Application No. 19133082.8, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-HK-12];

- 55. Hong Kong Patent Application No. 19132196.7, effective filing date of July 31, 2017 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-HK-13];
- 56. Singapore Patent Application No. 10201913959W, filed December 31, 2019 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-SG-14];
- 57. United States Patent Application No. 16/838,395, filed April 2, 2020 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-US-15];
- 58. United States Patent Application No. 17/345,390, filed June 11, 2021 entitled "Anti-KRAS G12D T Cell Receptors" [HHS Reference No. E-175-2016-0-US-16];
- 59. United States Provisional Patent Application No. 62/560,930, filed September 20, 2017 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-US-01];
- 60. PCT Application No. PCT/US2018/051641, filed September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-PCT-02];
- 61. Argentina Patent Application No. P180102695, effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-AR-03];
- 62. Taiwanese Patent Application No. 107133221, filed September 20, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-TW-05];
- 63. United States Patent Application No. 16/135,231, filed September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-US-06];

- 64. Australian Patent Application No. 2018335274 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-AU-07];
- 65. Brazilian Patent Application No. BR112020005469-0 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-BR-08];
- 66. Canadian Patent Application No. 3,076,339 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-CA-09];
- 67. Chinese Patent Application No. 201880060535.4 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-CN-10];
- 68. Costa Rica Patent Application No. 2020-0150 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-CR-11];
- 69. Eurasian Patent Application No. 202090652 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-EA-12];
- 70. European Patent Application No. 18792591.2 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-EP-13];
- 71. Israeli Patent Application No. 273254 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-IL-14];

- 72. Indian Patent Application No. 202047011647 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-IN-15];
- 73. Japanese Patent Application No. 2020-516422 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-JP-16];
- 74. Korean Patent Application No. 2020-7011112 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-KR-17];
- 75. Mexican Patent Application No. MX/a/2020/003117 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-MX-18];
- 76. New Zealand Patent Application No. 762831 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-NZ-19];
- 77. Singapore Patent Application No. 11202002425P effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-SG-20];
- 78. Hong Kong Patent Application No. 62020019700.7 effective filing date of September 19, 2018 entitled "HLA Class II-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-181-2017-0-HK-21];
- 79. United States Provisional Patent Application No. 62/594,244, filed December 4, 2017 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-US-01];

- 80. PCT Application No. PCT/US2018/063581, filed December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-PCT-02];
- 81. Australian Patent Application No. 2018378200 effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-AU-03];
- 82. Brazilian Patent Application No. BR112020011111-2 effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-BR-04];
- 83. Canadian Application No. 3,084,246, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-CA-05];
- 84. Chinese Application No. 201880087270.7, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-CN-06];
- 85. Costa Rican Application No. 2020-0287, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-CR-07];
- 86. Eurasian Application No. 202091335, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-EA-08];
- 87. European Application No. 18830062.8, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-EP-09];

- 88. Israeli Application No. 275031, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-IL-10];
- 89. Indian Application No. 202047026991, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-IN-11];
- 90. Japanese Application No. 2020-530325, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-JP-12];
- 91. Korean Application No. 2020-7019185, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-KR-13];
- 92. Mexican Application No. MX/a/2020/005765, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-MX-14];
- 93. New Zealand Application No. 765440, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-NZ-15];
- 94. Singapore Application No. 11202005236Q, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-SG-16];
- 95. United States Patent Application No. 16/769,144, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-US-17];

- 96. Hong Kong Patent Application No. 62021026617.2, effective filing date of December 3, 2018 entitled "HLA Class I-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-239-2017-0-HK-18];
- 97. United States Provisional Patent Application No. 62/749,750, filed October 24, 2018 entitled "HLA-A3-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-166-2018-0-US-01];
- 98. PCT Application No. PCT/US2019/057833, filed October 24, 2019 entitled "HLA-A3-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-166-2018-0-PCT-02];
- 99. Taiwanese Patent Application No. 108138456, filed October 24, 2019 entitled "HLA-A3-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-166-2018-0-TW-03];
- 100. United States Patent Application No. 16/662,808, filed October 24, 2019 entitled "HLA-A3-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-166-2018-0-US-04];
- 101. Australian Patent Application No. 2019364436, effective filing date of October 24,2019 entitled "HLA-A3-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-166-2018-0-AU-05];
- 102. Canadian Patent Application No. 3,116,749, effective filing date of October 24, 2019 entitled "HLA-A3-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-166-2018-0-CA-06];
- 103. European Patent Application No. 19805442.1, effective filing date of October 24,2019 entitled "HLA-A3-Restricted T Cell Receptors Against Mutated RAS" [HHS Reference No. E-166-2018-0-EP-07];

- 104. United States Provisional Patent Application No. 62/795,203, filed January 22, 2019 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12R Mutation" [HHS Reference No. E-029-2019-0-US-01];
- 105. Taiwanese Patent Application No. 109102511 filed January 22, 2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12R Mutation" [HHS Reference No. E-029-2019-0-TW-02];
- 106. PCT Application No. PCT/US2020/014382, filed January 21, 2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12R Mutation" [HHS Reference No. E-029-2019-0-PCT-03];
- 107. Australian Patent Application No. 2020211922, effective filing date of January 21,2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12RMutation" [HHS Reference No. E-029-2019-0-AU-04];
- 108. Canadian Patent Application No. 3,127,096, effective filing date of January 21, 2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12R Mutation" [HHS Reference No. E-029-2019-0-CA-05];
- Chinese Patent Application No. 202080010373.0, effective filing date of January
 21, 2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12R
 Mutation" [HHS Reference No. E-029-2019-0-CN-06];
- 110. European Patent Application No. 20705599.7, effective filing date of January 21,2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12RMutation" [HHS Reference No. E-029-2019-0-EP-07];
- Japanese Patent Application No. 2021-542206, effective filing date of January 21,2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12RMutation" [HHS Reference No. E-029-2019-0-JP-08];

- 112. Korean Patent Application No. 2021-7026169, effective filing date of January 21,2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12RMutation" [HHS Reference No. E-029-2019-0-KR-09];
- 113. United States Patent Application No. 17/424,591, effective filing date of January21, 2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12RMutation" [HHS Reference No. E-029-2019-0-US-10];
- 114. United States Provisional Patent Application No. 62/975,544, filed February 12, 2020 entitled "HLA Class I-Restricted T Cell Receptors Against RAS with G12D Mutation" [HHS Ref. No. E-031-2020-0-US-01];
- 115. PCT Patent Application No. PCT/US2021/017794, filed February 12, 2021 entitled "HLA Class I-Restricted T Cell Receptors Against RAS with G12D Mutation" [HHS Ref. No. E-031-2020-0-PCT-02];
- 116. Taiwanese Patent Application No. 110105194, filed February 12, 2021 entitled "HLA Class I-Restricted T Cell Receptors Against RAS with G12D Mutation" [HHS Ref. No. E-031-2020-0-TW-03];
- 117. United States Provisional Patent Application No. 62/976,655, filed February 14, 2020 entitled "HLA Class I-Restricted T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-074-2020-0-US-01];
- 118. PCT Patent Application No. PCT/US2021/017852, filed February 12, 2021 entitled "HLA Class I-Restricted T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-074-2020-0-PCT-02];
- 119. Taiwanese Patent Application No. 110105193, filed February 12, 2021 entitled "HLA Class I-Restricted T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-074-2020-0-TW-03];

- 120. United States Provisional Patent Application No. 62/981,856, filed February 26, 2020 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-088-2020-0-US-01];
- 121. PCT Patent Application No. PCT/US2021/019775, filed February 26, 2021 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-088-2020-0-PCT-02];
- 122. Taiwanese Patent Application No. 110106886, filed February 26, 2021 entitled "HLA Class II-Restricted T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-088-2020-0-TW-03];
- 123. United States Provisional Patent Application No. 63/050,931, filed July 13, 2020 entitled "HLA Class II-Restricted DRB T Cell Receptors Against RAS with G12D Mutation" [HHS Ref. No. E-165-2020-0-US-01];
- 124. PCT Patent Application No. PCT/US2021/041375, filed July 13, 2021 entitled "HLA Class II-Restricted DRB T Cell Receptors Against RAS with G12D Mutation" [HHS Ref. No. E-165-2020-0-PCT-02];
- 125. United States Provisional Patent Application No. 63/052,502, filed July 16, 2020 entitled "HLA Class II-Restricted DRB1*01:01 T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-172-2020-0-US-01];
- 126. PCT Patent Application No. PCT/US2021/041737, filed July 15, 2021 entitled "HLA Class II-Restricted DRB1*01:01 T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-172-2020-0-PCT-02];
- 127. United States Provisional Patent Application No. 63/086,674, filed October 2, 2020 entitled "HLA Class II-Restricted DQ T Cell Receptors Against RAS with G13D Mutation" [HHS Ref. No. E-189-2020-0-US-01];

- 128. PCT Patent Application No. PCT/US2021/053060, filed October 1, 2021 entitled "HLA Class II-Restricted DQ T Cell Receptors Against RAS with G13D Mutation" [HHS Ref. No. E-189-2020-0-PCT-02];
- 129. Taiwanese Patent Application No. "TBD", filed October 1, 2021 entitled "HLA Class II-Restricted DQ T Cell Receptors Against RAS with G13D Mutation" [HHS Ref. No. E-189-2020-0-TW-03]; and
- 130. United States Provisional Patent Application No. 63/060,340, filed August 3, 2020 entitled "HLA Class I-Restricted T Cell Receptors Against RAS with G12V Mutation" [HHS Ref. No. E-190-2020-0-US-01].

GROUP B

- United States Provisional Patent Application No. 62/565,383, filed September 29,
 2017 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-0-US-01];
- PCT Application No. PCT/US2018/051285, filed September 17, 2018 entitled "T
 Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-PCT-01];
- Australian Patent Application No. 2018342246 effective filing date of September 17,
 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-AU-02];
- Brazilian Patent Application No. BR112020006012-7 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-BR-03];
- Canadian Patent Application No. 3,077,024 effective filing date of September 17,
 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-CA-04];

- Chinese Patent Application No. 201880074539.8 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-CN-05];
- Costa Rican Application No. 2020-0170, effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-CR-06];
- Eurasian Application No. 202090757, effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-EA-07];
- European Patent Application No. 18780006.5 effective filing date of September 17,
 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-EP-08];
- Israeli Patent Application No. 273515 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-IL-09];
- Indian Patent Application No. 202047013911 effective filing date of September 17,
 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-IN-10];
- 12. Japanese Patent Application No. 2020-517556 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-JP-11];
- 13. Korean Patent Application No. 2020-7012344 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-KR-12];

- Mexican Application No. MX/a/2020/003504, effective filing date of September 17,
 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-MX-13];
- 15. New Zealand Patent Application No. 763023 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-NZ-14];
- Singapore Patent Application No. 11202002636P effective filing date of September
 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No.
 E-237-2017-2-SG-15];
- 17. United States Patent Application No. 16/651,242 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-US-16];
- 18. Hong Kong Patent Application No. 62020021272.3 effective filing date of September 17, 2018 entitled "T Cell Receptors Recognizing Mutated P53" [HHS Reference No. E-237-2017-2-HK-17];
- 19. United States Provisional Patent Application No. 62/867,619, filed June 27, 2019 entitled "T Cell Receptors Recognizing R175H or Y220C Mutation in P53" [HHS Reference No. E-135-2019-0-US-01];
- 20. PCT Application No. PCT/US2020/039785, filed June 26, 2020 entitled "T Cell Receptors Recognizing R175H or Y220C Mutation in P53" [HHS Reference No. E-135-2019-0-PCT-02];
- 21. Taiwanese Application No. 109121744, filed June 26, 2020 entitled "T Cell Receptors Recognizing R175H or Y220C Mutation in P53" [HHS Reference No. E-135-2019-0-TW-03];

- 22. United States Provisional Patent Application No. 63/074,747, filed September 4, 2020 entitled "T Cell Receptors Recognizing R273C or Y220C Mutation in P53" [HHS Reference No. E-173-2020-0-US-01];
- 23. PCT Patent Application No. PCT/US2021/048786, filed September 2, 2021 entitled "T Cell Receptors Recognizing R273C or Y220C Mutation in P53" [HHS Reference No. E-173-2020-0-PCT-02]; and
- 24. Taiwanese Patent Application No. "TBD", filed September 2, 2021 entitled "T Cell Receptors Recognizing R273C or Y220C Mutation in P53" [HHS Reference No. E-173-2020-0-TW-03].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

"Autologous T cell therapy products engineered by use of a CRISPR-nuclease to express a therapeutic T cell receptor claimed in the Licensed Patent Rights for the treatment or prevention of cancer in humans"

"Allogeneic T cell therapy products engineered by use of a CRISPR-nuclease to express a therapeutic T cell receptor claimed in the Licensed Patent Rights for the treatment or prevention of cancer in humans"

Specifically excluded from these fields of use are:

- Autologous, peripheral blood T cell therapy products engineered by transposonmediated gene transfer for the treatment of human cancers;
- 2. Autologous, peripheral blood T cell therapy products engineered via retrovirus and lentivirus-mediated gene transfer for the treatment of human cancer; and

3. Natural Killer T (NKT) cell therapy products engineered via viral and non-viral means for the treatment of human cancers. Wherein the NKT cell therapy product contains at least 50% NKT cells.

Intellectual Property Group A is primarily directed to isolated T cell receptors (TCRs) reactive to mutated Kirsten rat sarcoma viral oncogene homolog (KRAS), within the context of several human leukocyte antigens (HLAs). Mutated KRAS, which plays a well-defined driver role in oncogenesis, is expressed by a variety of human cancers, including pancreatic, lung, endometrial, ovarian and prostate. Due to its restricted expression in precancerous and cancerous cells, this antigen may be targeted on mutant KRAS-expressing tumors with minimal normal tissue toxicity.

Intellectual Property Group B is primarily directed to isolated TCRs reactive to mutated tumor protein 53 (TP53 or P53), within the context of several HLAs. *P53* is the archetypal tumor suppressor gene and the most frequently mutated gene in cancer. Contemporary estimates suggest that >50% of all tumors carry mutations in *P53*. Because of its prevalence in cancer and its restricted expression to precancerous and cancerous cells, this antigen may be targeted on mutant P53-expressing tumors with minimal normal tissue toxicity.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

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contain business confidential information and any release of information from these license

applications will be made only as required and upon a request under the Freedom of

Information Act, 5 USC 552.

Dated: October 21, 2021.

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